

United States Senate

WASHINGTON, DC 20510 JUN 23 P4:18

June 21, 1999

The Honorable Jane E. Henney, M.D.

Commissioner

Food and Drug Administration

Room 147, Parklawn Building

5600 Fishers Lane

Rockville, MD 20857

Re: Declaration of Ingredients in Surimi -- Proposed Rule (Docket No. 98P-0968)

Dear Commissioner Henney:

We write in support of the agency's proposed rule to permit the use of "and/or" ingredient labeling of the various fish species used in producing surimi and processed seafood products containing surimi. (Food Labeling: Declaration of Ingredients, 64 Fed. Reg. 17,295, Apr. 9, 1999). The proposed rule responds to a Citizen Petition submitted by the National Fisheries Institute (NFI) in October 1998. We have a keen interest in the Food and Drug Administration's (FDA) action on this matter.

Section 403(I)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 343(I)(2)) authorizes FDA, pursuant to delegation from the Secretary of Health and Human Services, to promulgate regulations establishing exemptions from the usual requirement of specificity in ingredient labeling of food when compliance with the usual requirement is impracticable, or results in deception or unfair competition. A regulatory exemption, such as the agency has proposed, permitting "and/or" declaration of the fish species that might be present in surimi and surimi-containing processed seafoods is entirely consistent with, and merited under, this statutory authority. The surimi industry, through NFI's petition, has made a convincing case that the vagaries of fish species availability and the burdens of contingent labeling of finished seafood products makes specificity in ingredient labeling impracticable.

We have one concern about the agency's proposed rule, however. FDA has suggested that a term such as "fish protein" could be used to designate collectively in ingredient labeling the fish species used in the production of surimi -- for example: "fish protein (contains one or more of the following: pollock, cod and/or Pacific whiting)." The NFI and the surimi industry inform us that "fish protein" is not the most advantageous and suitable collective term to designate the fish ingredient in surimi and surimi-containing processed seafood products across all labeling contexts. In particular, such a term may mislead consumers by confusing surimi with another product "fish protein concentrate", which is used for entirely different purposes. A simpler and more direct term, such as "fish", may be more appropriate and more informative to the consumer. In finalizing its regulation, we urge the agency to give serious attention to this industry concern, and ultimately to settle on an exemplary collective term that best suits all foreseeable labeling uses.

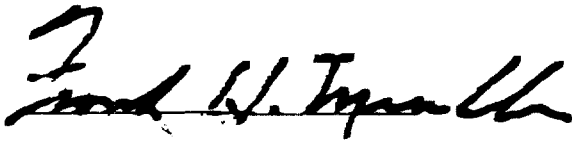
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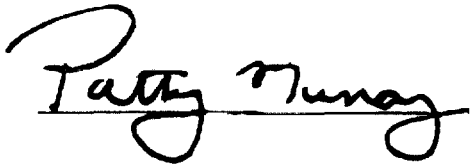
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We further urge FDA to finalize a regulation that authorizes "and/or" ingredient labeling of surimi and processed seafood products containing surimi as expeditiously as possible. Consistent with explicit Congressional direction reflected in the October 1998 Conference Report accompanying H.R. 4101 (making appropriations for FDA programs for the fiscal year ending September 30, 1999), we expect this rule making to be completed and a final rule promulgated and effective no later than October 1999. Moreover, believing an exemption permitting "and/or" ingredient labeling ultimately will be deemed proper by FDA, we would support and recommend, as an interim measure and exercise of agency enforcement discretion, permitting industry to transition to this labeling practice immediately so as to quickly alleviate unwarranted burdens. Precedent for this administrative approach may be found in FDA's advice that "and/or" ingredient labeling of nutritive sweeteners in soft drinks may be employed pending completion of that rule making.

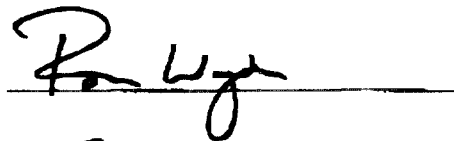
Thank you for your attention to these comments.

Sincerely,













U.S. Senator Ron Wyden



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From: Kola Garber

Subject: Declaration of Ingredients in Surimi **Pages:** 3

(Including cover)

COMMENTS:

We are sending a hard copy this afternoon. Please expect the fax to meet the deadline of today (June 23rd) for our comments.

Thank you in advance for your assistance,
Kola